### Mullins, Diona (CHFS Health Policy)

From:

Orme, Tricia L (CHFS OLS)

Sent:

Tuesday, July 07, 2015 8:15 AM

To:

Mullins, Diona (CHFS Health Policy)

Subject:

Mailed Comments yesterday

Attachments:

DOC000.pdf; DOC001.pdf; DOC002.pdf; DOC003.pdf

#### Diona,

Attached are several comments I received in the mail yesterday. They all look to be new comments.... DOC003 has several comments in the same attachments. They were all mailed together so I scanned them together. Thanks!

Tricia Orme
Administrative Specialist III
Office of Legal Services
275 East Main Street, CHR 5W-B
Frankfort, KY 40621
502-564-7905 ext: 3421
502-564-7573 (fax)

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# City of Frankfort

FIRE & EMERGENCY MEDICAL SERVICES

DISASTER & EMERGENCY SERVICES

300 West Second Street, Ste. 3 Frankfort, Kentucky 40601 (502) 875-8511 Fax: (502) 875-8533 www.frankfort.ky.gov **Mayor** William I. May, Jr.

Commissioners Lynn Bowers Tommy Z. Haynes Robert E. Roach John R. Sower

July 2, 2015

Tricia Orme
Cabinet for Health and Family Services
Office of Legal Services
275 East Main Street, 5W-B
Frankfort, Kentucky 40621

Dear Ms. Orme,

I would like to take the opportunity to support the Kentucky Ambulance Providers Association (KAPA) stance opposing the amendment to 900 KAR 5:020 and the state health plan ground ambulance review criteria. I have included the opposition statement from KAPA.

I have concerns that the plan places all providers in a broad category. I am not qualified to make a determination of the effect the changes will have on physicians' offices and clinics. However, I think the proposed Cabinet changes could be devastating for organizations like Frankfort Fire and EMS that are already operating at a loss to provide the traditional 911 services. It is unrealistic to use a "one size fits all" approach to this issue.

Sincerely,

Eddie Slone Fire Chief

Frankfort Fire and EMS

# KENTUCKY AMBULANCE PROVIDERS ASSOCIATION ISSUES STATEMENT

# OPPOSITION TO THE PROPOSED AMENDMENT TO 900 KAR 5:020 & THE STATE HEALTH PLAN GROUND AMBULANCE REVIEW CRITERIA

ISSUE: The Cabinet for Health and Family Services ("Cabinet") proposes to delete the Ground Ambulance Review Criteria from the State Health Plan. By doing so, it substantially relaxes the standards by which new ambulance services would be reviewed. Such action adversely impacts existing public and private ground ambulance services as well as the health, safety, and welfare of Kentucky citizens.

- Currently, a CON application seeking to establish or expand a ground ambulance service is processed through full, formal review. Under formal review, the applicant has the burden of proof to show that the application is consistent with all five of the statutory criteria: (1) Consistency with the State Health Plan; (2) Need and Accessibility; (3) Interrelationships and Linkages; (4) Costs, Economic Feasibility, and Resources Availability; and (5) Quality. Either the applicant or an affected party may request a hearing on an application being processed under formal review.
- The proposed revision to the SHP Ground Ambulance Review Criteria does not remove
  the establishment or expansion of a ground ambulance service from the CON process but
  changes review to the expedited, non-substantive review process.

Under non-substantive review, need for the proposal is presumed. The affected party, not the applicant, has the burden of proof to rebut the presumed need for the proposal by a preponderance of the evidence. The applicant would no longer be required to prove that the application is consistent with: (1) Consistency with the State Health Plan; (3) Interrelationships and Linkages; (4) Costs, Economic Feasibility, and Resources Availability; and (5) Quality. Further, only affected parties may request hearings on CON applications awarded non-substantive review. Without evidence of a provider's ability to provide services in a quality manner, the health, safety, and welfare of Kentucky citizens could be compromised. Further, it may result in providers unexpectedly exiting the market due to financial constraints, which could limit access to ground ambulance services and potentially impact the ability of existing providers to continue to operate.

The proposed revisions could have a devastating impact on existing public, governmental ground ambulance providers. Public, governmental ambulance providers are funded through tax dollars. They perform the majority, if not all, 9-1-1 emergency runs at a financial loss. These financial losses are offset by income earned on non-emergent, scheduled transports. With processing and approval of new providers under the non-substantive review process, it would be easier for new providers to enter a market and "cherry pick" the more profitable non-emergent scheduled transports. If this occurs, public, governmental ground ambulance providers could be forced to seek tax increases

to offset their financial losses or be forced to cease providing services. Such a result could negatively impact the providers and communities they serve.

• The Cabinet filed a proposed amendment to 900 KAR 5:020 The State Health Plan for Facilities and Services ("SHP") along with a red-lined version. The proposed changes will be published on June 1, 2015, in the Administrative Register of Kentucky. The current SHP Review Criteria for Ground Ambulance providers is:

An application for ground ambulance services shall be consistent with this Plan if the following criteria are met:

- 1. The applicant shall document that the appropriate local legislative body (fiscal court, city council, or both if applicable) has been given notice of the applicant's intent to obtain a certificate of need. The notice shall describe the scope of service and proposed service area. For purposes of this requirement, the term "appropriate local legislative body" refers only to those legislative bodies that are currently licensed to provide ambulance services in the applicant's proposed service area;
- 2. In the event of competing applications to add services in the same service area, preference shall be given to an application proposing the higher level of service. If multiple providers propose ALS services, then preference shall be given to the applicant who most thoroughly documents need for the service and presents ability to meet the need; and
- 3. Applications to provide only Class II or Class III services shall be accompanied by documentation (e.g., charts depicting response times of existing service, number of runs during the previous year, and comparable supportive data) that the need for scheduled or critical care inter-facility transportation is not being met by the existing emergency or other Class II or III ground ambulance services. In the presence of this evidence, priority shall be given to a competing application, if any, for the addition of vehicles, expansion of service areas, or comparable modifications that would allow an existing emergency ambulance service provider to meet any unmet need for critical care interfacility or scheduled ambulance services.

# JESSAMINE COUNTY JUDGE/EXECUTIVE DAVID K. WEST

Court House - 101 North Main Street Nicholasville, KY 40356 (859) 885-4500 • Fax (859) 885-2545 Email: dwest@jessamineco.com www.jessamineco.com

June 29, 2015

Tricia Orme Office of Legal Services 275 East Main Street 5 W-B Frankfort, KY 40601

Dear Ms. Orme:

As Jessamine County Judge Executive, please accept this letter as official notification of my opposition to the amendment to 900 KAR 5:020, the State Health Plan for facilities and services.

The proposed amendment would potentially result in private, competing ambulance providers being permitted to operate in Jessamine County and developing contracts with medical facilities such as nursing homes or rehabilitative centers, making the agency the sole provider for said facility. This would result in a decrease in our county EMS agency's run volume and thereby a decrease in our revenue stream. Any decrease in revenue would have a direct negative impact on our county EMS agency and our county budget. As a current holder of a Certificate of Need who has developed an Emergency Medical Services system under the Certificate of Need regulations during a very challenging reimbursement period, we feel that allowing others to provide ambulance services in Jessamine County without a Certificate of Need could potentially reduce our revenue by up to 30 percent or \$500,000.

What concerns me more than the potential loss in revenue is the fact Jessamine County would have no control over the quality of service being provided to our citizens by a private company, nor would our residents be exempt from balanced billing from a private service. Currently our residents are not billed the remainder outside of their insurance payment for EMS service. Relaxing the CON review standards would permit a competing EMS provider to operate in our county which would result in a huge financial burden to our citizens that we, as a county government, have worked diligently to relieve.

In closing, I feel the current system is not broken and has served as an effective means of checks and balances. The proposed amendment will weaken the current CON review process and requirements by removing the more stringent class I, II, III, and IV review processes and replacing them with the lesser class VI standards for all CON requests. I cannot, in good conscience, support a weakening of any review process that directly affects the health and safety of our Jessamine County residents.

For these reasons I, and in agreeance with our Jessamine County EMS' administration, do not support the removal of the ambulance services section as proposed from 900 KAR 5:020.

Sincerely, David K West

David K. West,

Jessamine County Judge/Executive

DKW:krw

Dale McCreary, Director
Franklin-Simpson County Ambulance Service
417 Macedonia Rd. Franklin, Ky. 42134

06-30-15

Tricia Orme
Office of Legal Services
275 East Main Street 5 W-B
Frankfort, KY 40601

Dear Ms. Orme:

Our EMS agency opposes the amendment to 900 KAR 5:020, the State Health Plan for facilities and services.

As a current holder of a Certificate of Need who has developed an Emergency Medical Services system under the Certificate of Need regulations during a very challenging reimbursement period, we feel that allowing others to provide ambulance services in the area where we have been operating without a Certificate of Need could potentially reduce our revenue by \$100,000 a year. This could potentially jeopardize the availability of ambulance services in the area in which we operate.

For this reason we do not support the removal of the ambulance services section as proposed from 900 KAR 5:020.

Respectfully,

Dale McCreary

Dal Mchen FSEMS Discours



Stephen A. Besson, M.D. Andrew R. Usery, M.D.

WM. Frank McKemie, Jr. MD, Emeritus

Lauren D. Blackwell, DO Sarah Lindsay Florence, APRN

June 22, 2015

To Whom It May Concern:

Re: Harrison Memorial Hospital - Cardiovascular Certificate of Need

Over the past several months, the citizens of Harrison. Nicholas, and Robertson counties have had the benefit of increased cardiovascular services at Harrison Memorial Hospital, including diagnostic heart and peripheral vascular catheterization services.

Under the direction of Dr. Matthew Shotwell, our expanded service lines have helped our patients enjoy a better quality of life, and directly impacted our ability to help patients with critical diseases, such as myocardial infarctions, acute coronary syndromes, and severe peripheral arterial disease.

I can attest that scores of my patients have been able to enjoy the benefit of locally available state-of-the-art cardiac care.

I can also tell you that I have had several patients whose lives have literally been saved by our ability to intervene in their care in this community.

l, along with the rest of the medical staff at Harrison Memorial Hospital would strongly wish that we could expand our service lines even further to provide interventional cardiac catheterization services and further impact the health and mortality of our community in a positive way.

Thank you in advance for your attention in this matter.

Sincerely.

Sterfich A. Besson, MD

# HMH Physician Group

Michael S. Gainey, MD, Primary Care Tel (859)234.4494 • Fax (859)234.4498

F. Daniel Mongiardo, MD, ENT Tel (859)235.3600 • Fax (859)234.3967

James Pettey, MD, Orthopaedics Tel (859)234.1707 • Fax (859)234.1768

22 June 2015

To: Whom It May Concern

RE: Interventional Cardiac Catherization Lab

From: James Pettey, M.D.

Please allow me to lend my support toward authorization of the request by Harrison Memorial Hospital (IIMH) in Cynthiana Kentucky to provide interventional cardiology services.

As you may be aware, HMH offers a state of the art cardiac catheterization facility capable of advanced interventional procedures such as stent placement. We have the distinct privilege of having a skilled and experienced interventional cardiologist, Dr. Matthew Shotwell, on our staff.

It is my honor to be serving as the chief of the medical staff here at Harrison Memorial Hospital, and it is my opinion that our entire medical staff is in agreement that providing interventional cardiology services here would greatly enhance the welfare of patients not only in Harrison County but also in surrounding counties with limited access to healthcare and dependent on HMH for definitive cardiology services.

As Dr. Shotwell can explain far better than I, in ischemic myocardial disease, minutes equal muscle. Many of our acute cardiac patients simply cannot tolerate the additional time that transportation to Lexington entails and as a result, would incur additional irreversible myocardial damage. This tragedy would be totally preventable by timely, safe, and appropriate cardiac intervention allowing rapid reestablishment of myocardial blood flow which can be easily provided here at Harrison Memorial Hospital.

As a retired USAF orthopaedic surgeon, I can attest that all branches of the military now subscribe to the doctrine of providing near immediate initial surgery for battle injured military members. We now place mobile surgical facilities within minutes of a battle zone. It has been proven that rapid control of hemorrhage and reestablishment of blood flow as soon as possible results in far more viable skeletal muscle and organs, and vastly increases survival rates. It is the same with myocardial tissue.



Michael S. Gainey, MD, Primary Care Tel (859)234.4494 • Fax (859)234.4498

F. Daniel Mongiardo, MD, ENT Tel (859)235.3600 • Fax (859)234.3967

James Pettey, MD, Orthopaedics Tel (859)234.1707 • Fax (859)234.1768

I strongly urge you to grant approval of the request for Harrison Memorial Hospital to provide interventional cardiac services. This action will have an extremely positive effect on the outcome of our patients and greatly enhance the healthcare of the citizens of our great Commonwealth.

Sincerely,

James Pettey, M.D.

Col. (retired), USAF, MC,FS

### To Whom It May Concern:

I am M.S. Gainey MD in Cynthiana Ky. I have been affiliated with Harrison Memorial Hospital for over 20 years.

This letter is in reference to our local independent hospital, Harrison Memorial Hospital. Cynthiana Ky. Dr. Matt Shotwell, interventional Cardiologist, has been on staff since January 2015. Since his arrival at Harrison Memorial as a full time Cardiologist, patient care has improved significantly with the patients who have had complaints of chest pain, having hypertension and or peripheral vascular disease. Currently Dr. Shotwell has done intervention of peripheral vessels as well as renals to increase circulation of bilateral lower extremities and decrease blood pressure. Dr. Shotwell has been able to perform diagnostic heart catheterizations on local residents that have entered our doors and prevented them unnecessary travel unless intervention is or was needed. With high rates of diabetes mellitus, tobacco abuse and high cholesterol in our area, this has been a terrific service to offer our patients. With Dr. Shotwell on staff and using him at his full potential as a interventional Cardiologist we can improve patient care and potential outcomes for our community.

Sincerely,

MS Gainey MD

In S Sastins

A. C. Wright, M.D., P. S. C.
A. C. Wright, M.D.
Stephen A. Moses, M.D.
430 E. Pleasant St. ~ Cynthiana, KY 41031
Phone: 859-234-3282 ~ Fax: 859-234-9400

June 23, 2015

RE: Certificate of Need

To Whom It May Concern:

I am a full time family medicine physician in Cynthiana, KY and am affiliated with Harrison Memorial Hospital. On a daily basis I see patients with high blood pressure, diabetes, and high cholesterol; these are just a few of the risk factors for heart disease. Since January 2015 our hospital has benefitted from the full time presence of Dr. Matthew Shotwell who is providing cardiology services. During this time Dr. Shotwell has performed diagnostic catheterizations that have allowed for timely diagnoses and decision making in helping not just my patients but the patients of my fellow physicians. While the cardiac catheterization lab at Harrison Memorial Hospital has existed for several years it has largely gone underutilized until Dr. Shotwell arrived.

Now your help is needed. By granting a certificate of need for use of our cardiac catheterization lab for more than just diagnostic procedures the residents of Cynthiana and surrounding communities will benefit. Not only will our patients benefit from the interventions Dr. Shotwell can provide, they will benefit from the timely access to records that this will provide for physicians. They will also benefit from the ability to stay closer to home. I myself have had multiple patients who have had to wait nearly 72 hours for transfer to an outside hospital after having a heart attack; those were the days prior to Dr. Shotwell. Granting a certificate of need for cardiac interventions will allow all of us to take better care of our patients.

Sincerely,

Stephen A. Moses, M.D.

SAM/rs

# **CARDIAC CATHETERIZATION STANDARDS IN OTHER STATES**

New Hampshire Standards for Adult Cardiac Catheterization Laboratory Services. Ch. He-Hea 1102.02, "Quality Assurance Requirements"

- (a) Any applicant for adult cardiac catheterization laboratory services shall demonstrate the availability of a quality assurance plan to objectively and systematically monitor patient care.
- (b) Demonstration of a quality assurance plan shall be made by submitting with the application a copy of an existing or proposed plan specific to the adult cardiac catheterization laboratory services begin offered which is consistent with the hospital-wide quality assurance plan.
- (c) The quality assurance plan shall
  - 1. Contain patient selection criteria by procedures;
  - 2. Contain formal transfer agreements per He-Hea 1102.01(c)(2), and emergency protocols for transfer to another facility which:
    - a. Specify the protocol for transfer to another facility; and
    - b. Include the following:
      - i. Signature of both hospitals; and
      - ii. Dated with the past 12 months of submission with the application;
  - 3. Describe the mentoring program for licensed physicians, which shall include operator volume requirements; and
  - 4. Describe the process of cross-facility case review and outcomes analysis with the receiving facility for patients that have been transferred. "

\*\*\*\*

# Georgia - State Health Plan and CON Rules for Adult Cardiac Catheterization 111-2-2-.21

- "(1) An application for a new or expanded adult cardiac catheterization service must agree in writing to the following conditions:
  - establishment and maintenance of a system of continuity of care and coordinator of service, as evidenced by regular and ongoing planning and quality improvement sessions with community health providers and advocacy programs;
  - 2. participation in a data reporting, quality improvement, outcome monitoring, and peer review system within the application or DTRC [diagnostic, treatment, or rehabilitation center] as well as a national, state or multiprogram system which benchmarks outcomes based on national norms and which shall be named in the application and which provides for peer review between and among professional practicing in facilities and programs other than the applicant hospital or DTRC;...."

Maryland State Health Plan for Facilities and Services: PCI Services, pp. 46-48

#### D. Primary PCI Services

#### (5) Quality

- (a) The hospital shall develop a formal, regularly scheduled (meetings at least every other month) interventional case review that requires attendance by interventionalists and other physicians, nurses, and technicians who care for primary PCI patients
- (b) The hospital shall create a multiple care area group (emergency department, coronary care unit, and cardiac catheterization laboratory) that includes, at a minimum, the physician and nursing leadership of each care area and meets monthly to review any and all issues related to the primary PCI system, identify problem areas, and develop solutions.
- (c) At least semi-annually, as determined by the Commission, the hospital shall conduct an external review of at least five percent of randomly selected PCI cases performed in the applicable time period.
- (d) The hospital shall evaluate the performance of each interventionalist through an annual review of:
  - i. At least 10 cases or 10 percent of randomly selected PCI cases performed by the interventionalist, whichever is greater; or
  - ii. If fewer than 10 cases have been performed, then all cases shall be reviewed.
- (e) The performance review shall:
  - i. Include a review of angiographic images, medical test results, and patients' medical records; and
  - ii. Be conducted by a reviewer who meets all standards established by the Commission to ensure consistent rigor among reviewers.
- (f) Hospital shall provide annually, or upon request, a report to the Commission that details its quality assurance activities, including internal peer review of cases and external review of cases.
  - i. The hospital shall demonstrate that it has taken appropriate action in response to concerns identified through its quality assurance processes.
  - ii. All individually identifiable patient information submitted to the Commission for the purpose described in this subsection shall remain confidential.
  - iii. Physician information collected through the peer review process that is submitted to the Commission for the purpose described in this subsection shall remain confidential.

\*\*\*\*

# Illinois <u>Health Care Facilities Plan Section 1110.1330 Cardiac Catheterization Review</u> Criteria

a) "Peer Review" - Review Criteria

Any applicant proposing the establishment or modernization of a cardiac catheterization unit shall detail in its application for permit the mechanism for adequate peer review of the program. Peer review teams will **evaluate the quality** of studies and related morbidity and mortality of patients and also the technical aspects of providing services such as film processing, equipment maintenance, etc.

\*\*\*\*

# Tennessee SHP CON Standards and Criteria for Cardiac Catheterization Services, p. 13

4. **Quality Control** and Monitoring: Applicants should document a plan to monitor the quality of its cardiac catheterization program, including, but not limited to, program outcomes and efficiency. In addition, the application should agree to cooperate with quality enhancement efforts sponsored or endorsed by the State of Tennessee, which may be developed per Policy Recommendation 2.

#### At p. 20

4. Quality Control and Monitoring: The Division had considered requiring applicants to participate in the NCDR. Respondents to the Questionnaire agreed with the intent of such a requirement, however most indicated that the costs of participation in NCDR is burdensome, especially for new cardiac cath programs. Consequently, this standard seeks to ensure that applicants will develop a comprehensive quality control system that best fits their circumstances and that applicants participate in ongoing efforts to improve the overall quality of cardiac care in TN.

61362693.1 61362790.1

### Mullins, Diona (CHFS Health Policy)

From:

Orme, Tricia L (CHFS OLS)

Sent:

Tuesday, July 07, 2015 7:57 AM

To:

Mullins, Diona (CHFS Health Policy)

Subject:

FW: Proposed Changes in CON Laws

Attachments:

bcems con change It01.doc; Proposed CON opposition.doc

Please let me know if you are going to consider these because they are late. Also, I have several I'm going to scan you that I received in the mail yesterday. Thanks!

From: Brent A, Jaynes [mailto:bajaynes@windstream.net]

**Sent:** Monday, July 06, 2015 2:01 PM

To: Orme, Tricia L (CHFS OLS)

Subject: Proposed Changes in CON Laws

Please accept the two attachments as our comments opposing the proposed Changes in the CON Law.



Brent A. Jaynes
Executive Director
P.O. Box 153
592 Bladeston Drive
Brooksville, KY 41004
(Office) 606-735-3783
(Fax) 606-735-2694
(Cell) 606-462-0018



# BRACKEN COUNTY EMS

## 592 Bladeston Drive P.O. Box 153 Brooksville, KY 41004 emsbracken@windstream.net

Office (606) 735-3783

Fax (606) 735-2694

Brent A. Jaynes, Director

Kelly D. Muse, Assistant Director

June 30, 2015

Ms. Tricia Orme Cabinet for Health and Family Services Office of Legal Services 275 East Main Street Frankfort, KY 40602

RE: Change to CON Procedure Covering Ground Ambulance Service.

Bracken County EMS is a Special Purpose Government Entity which is the sole provider of both emergency and non-emergency transports for Bracken County and parts of Robertson County.

Our service depends greatly on the fees received from these transports to enable us to continue to serve the citizens of our county.

With the proposed changes in the law, new ambulance services will be allowed to establish in an area without those which we serve having an ability to question the need for the additional service.

This could result in down grading of the services which are provided to the citizens with the possibility of raising taxes to keep the standards of established services to par or above.

Bracken County EMS stands strongly with the additional comments from the Kentucky Ambulance Provider's Association submitted to the Cabinet on June 30, 2015.

Please consider our agency to not support the proposed changes as it will surely be detrimental to the standard of care and services in which we provide.

Sincerely,

Brent A. Jaynes Executive Director

**Bracken County EMS** 

# EDWARD C. SCHUMANN Attorney At Law 5600 Cutters Trace Melbourne, Kentucky 41059 (859)635-8682 ecs262cutters@fuse.net

June 22, 2015

Ms. Tricia Orme
Cabinet for Health and Family Services
Office of Legal Services
275 East Main Street, 5W-B
Frankfort, KY 40602
By e-mail to tricia.orme@ky.gov

RE: Change to CON Procedure Covering Ambulance Services

Dear Office of Legal Services (Tricia Orme):

I am the attorney for Bracken County Emergency Medical Service (BCEMS). BCEMS is a Special Purpose Government Entity and a Taxing District established to provide ambulance service to all of Bracken County, Kentucky.

This letter conveys my feelings concerning the change to the CON procedures for Ambulance service providers. If we no longer have the ability to question the authority of an ambulance service provider to operate in our geographical area it will create the following problems that will impact our county and its residents:

- 1. It will create a potential down grade of the services offered to the taxpayers in our county;
- 2. It has the potential to increase taxes to our taxpayers if the new service providers select only the most profitable runs to make; and
- 3. It will not allow BCEMS or any resident of Bracken County to have a voice in what ambulance provider is going to provide service to the County.

While these are not the only concerns that I have these are the ones that I feel are most harming to the County and its residents.

Thanks for taking the time to listen to our concerns.

Sincerely,

/s/ Edward C. Schumann